

## Clinical Research as a Learning Industry

By Norman M. Goldfarb

The recent Partnerships in Clinical Trials conference provided an excellent opportunity to assess the clinical research industry's efforts to address the significant challenges it faces in bringing effective medical treatments to market in a reasonable period of time and at a reasonable cost. Many of these challenges have not changed in the past 20 years, and some have even worsened. For example, study participant retention is at record lows. Even incremental improvements come slowly, but nothing less than reinvention is needed.

Fortunately, we may be entering a new era of clinical research innovation. (See: "The Golden Age of Clinical Research Innovation" in the March 2014 issue of the Journal.) However, innovation is only part of the solution. We also need to propagate innovation throughout the industry. The concept of the *learning enterprise* is nothing new, but what we need now is a *learning industry*. We cannot rely on innovation to trickle down from a few innovative organizations — or the innovators within organizations that are not generally innovative. A more concerted approach is required. Even the most innovative organizations are held back by a static industry. A rising tide lifts all ships, but it is very difficult to raise any ship much above the water.

TransCelerate BioPharma, for example, is applying the concept of "pre-competitive" activities broadly; its members recognize that, in many areas of clinical research, slightly different methods are more of a burden than a competitive advantage. Model Agreements & Guidelines International (MAGI) has developed numerous standardized forms and other documents free for use by anyone in the industry. The Joint Task Force for Clinical Trial Competency (JTFCTC), the Multi-Regional Clinical Trials (MRCT) Center, the Alliance for Clinical Research Excellence and Safety (ACRES), and other industry initiatives are also working to solve industry problems. (See "Clinical Research Innovation Initiatives" in the November 2012 issue of the Journal.)

Organizations and entire industries learn in a six-step process:

- **Participation** requires recognition that a learning industry benefits the specific organization and should include broad participation, including regulators and patients.
- **Commitment** requires management support of learning as a lucrative investment deserving of time and resources.
- **Innovation** requires problem recognition, assessment of existing solutions, identification of potential improvements, experimentation, and creation of better solutions.
- **Implementation** requires documentation (e.g., SOPs) for reproducibility and metrics to confirm that a solution does, in fact, solve a problem.
- **Propagation** requires generalization of solutions (standardization), communication that the solutions exist, training (including publications and lessons-learned databases), incorporation of solutions in software applications, and recognition of the contributors.
- **Evolution** requires an iterative process of improving the solutions, as well as the process of learning itself.

Moving innovation and learning from the individual to the organization to the industry requires a broadening of perspective. When, for example, a study coordinator finds a better

way to communicate a difficult concept in an informed consent form, he or she should want to — and be able to — spread that innovation to other studies throughout the industry. This type of innovation occurs constantly, but without an established industry-wide learning process, most innovations just reinvent the wheel in various shapes, few of them very round.

We are currently caught in a vicious cycle, in which ineffective methods consume the time that could be used for innovation and learning. We need to move to a virtuous cycle, in which innovation and learning create time for more innovation and learning. Can we take this leap of faith?

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